IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 5 CASES LISTED IN PLAINTIFFS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF STEVEN GOLDWASSER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") respectfully submit this Memorandum in Opposition to Plaintiffs' Motion to Exclude or Otherwise Limit the Opinions and Testimony of Defense Expert Steven Goldwasser, M.D. ("Dr. Goldwasser"). (Pls.' Motion [ECF No. 4365]; Exs. A-F [ECF Nos. 4365-1, 4365-2, 4365-3, 4365-4, 4365-5, 4354-6]; Memorandum [ECF No. 4372].)[1]

INTRODUCTION

Plaintiffs seek to bar the testimony of Dr. Goldwasser, who Ethicon offers as a general expert on the design, safety, and efficacy of TVT and TVT-Exact. Plaintiffs support their motion by mischaracterizing the scope and basis for Dr. Goldwasser's opinions – incorrectly claiming he provides opinions about FDA regulations and suggesting his opinions on material properties of

[1] Because Plaintiffs' Motion "adopt[s] and incorporate[s]" their Wave 4 Motion to Exclude Expert Testimony of Dr. Goldwasser and their Memorandum of Law in support thereof, Pls.' Motion [ECF No. 3677]; Exs. A-C [ECF Nos. 3677-1, 3677-2, 3677-3]; Memorandum [ECF No. 3678], Ethicon hereby adopts and incorporates its Memorandum of Law in Opposition to Plaintiffs' Wave 4 Motion [ECF No. 3754].

polypropylene mesh are based solely on his personal experience. Contrary to Plaintiffs' framing of these opinions, Dr. Goldwasser properly combines his experience as a surgeon, teacher, and inventor and his review of the medical literature – including Level 1 studies – to not only identify the commonly known risks but to opine on whether the IFUs of TVT and TVT-Exact disclose those enumerated risks from a clinical perspective. Likewise, Dr. Goldwasser's experience and review of the literature qualifies him to challenge the scientific basis for Plaintiffs' assertions that Ethicon's mesh devices' material properties, including degradation, mesh contraction, cytotoxicity, and laser and mechanical cut mesh, have negative clinical impact on patients. Ultimately, his opinions would be very instructive to the jury and should be admitted at trial.

DR. GOLDWASSER'S BASES FOR HIS EXPERT OPINION

Dr. Goldwasser is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. (Pls.' Ex. B (Goldwasser Report) at 1.) He completed his residency in obstetrics and gynecology and is fellowship trained in female pelvic medicine and reconstructive surgery. (*Id.*) He started the division of Urogynecology at the University of Florida and continues to teach there as a clinical instructor. (*Id.*) Dr. Goldwasser has been trained in a large variety of female pelvic medicine and reconstructive treatment "including vaginal, abdominal, laparoscopic, robotic, and non-surgical approaches for treating pelvic organ prolapse and urinary incontinence." (*Id.* at 2.) In addition, he has been trained on various testing, including urodynamic testing, uroflowmetry, post-void residual measurements, cystometric testing, leak point pressure measuring, and pressure flow studies. (Pls.' Ex. D (Goldwasser Dep.) 13:6-14:4.) During his training and career, Dr. Goldwasser has designed and implemented various techniques involving native tissue repair and augmentation procedures

using biologic graft and synthetic graft materials. (*Id.* at 2.) These experiences led to Dr. Goldwasser developing and implementing devices and techniques for reconstructive pelvic surgery, including co-inventing EXAIR, a novel polypropylene mesh graft-based approach for treating vaginal prolapse. (*Id.* at 4.)

Thus far in his surgical career, Dr. Goldwasser has performed "easily over 1000 TVT procedures (predominantly the original TVT and the TVT Exact) with excellent results." (*Id.* at 3.) His current "retropubic sling of choice" is the TVT Exact, which he continues to perform on a weekly basis. (*Id.*) If complications arise, Dr. Goldwasser has experience treating and managing those complications. (*Id.* at 4; Pls.' Ex. D (Goldwasser Dep.) 121:13-122:16.)

Dr. Goldwasser's report combines this extensive clinical experience with a reliance upon a large pool of scientific literature and studies as well as the evaluation of many physicians and medical organizations to form opinions to a reasonable degree of medical certainty. (Pls.' Ex. B (Goldwasser Report) at 1, 4.) The materials Dr. Goldwasser cites include Level 1 evidence and the official statements of medical societies. In addition to the materials directly cited in his report, Dr. Goldwasser also reviewed extensive amounts of medical literature identified on his reliance list. (*See generally* Pls.' Ex. E (General Reliance List).) Plaintiffs themselves acknowledge that Dr. Goldwasser's reliance list includes over 900 articles. (Pls.' Memorandum at 12; Pls.' Ex. D (Goldwasser Dep.) 43:22-44:10.) In short, Dr. Goldwasser's opinion merges his extensive training and experience as a surgeon, teacher, and inventor with an exhaustive wide-ranging review of the medical literature.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review of *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. Dr. Goldwasser is qualified to opine about the completeness of TVT's and TVT-Exact's warnings from a clinical perspective based on his education, training, clinical practice, and review of the medical literature.

Contrary to what Plaintiffs suggest, Dr. Goldwasser does not offer opinions on the "adequacy" of TVT's and TVT-Exact's labeling. Ethicon acknowledges this Court's prior rulings excluding urogynecologists and urologists from testifying about the "adequacy" of IFUs. *See, e.g.*, *Bethune v. Boston Sci. Corp.*, 2016 WL 2983697, at *5, 14-15 (S.D. W. Va. May 20, 2016); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *2 (S.D. W. Va. Aug. 30, 2016). Nevertheless, this Court has consistently held that they may testify about the specific risks associated with the product and whether those risks appeared in the IFU. *See, e.g.*, *Edwards*, 2014 WL 3361923, at *13-14 ("Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU[,] . . . to render an opinion as to the completeness . . . of Ethicon's warning"). Dr. Goldwasser seeks to do just that – testify about the completeness of the warnings from the clinical perspective in light of the knowledge common to the relevant medical community. As this Court has previously recognized, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–

02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)). Moreover, the governing legal standard underlying Plaintiffs' claims *require* the identification of those risks that are outside the scope of a device manufacturer's duty to warn because they are commonly known to surgeons who use the device at issue. It is this testimony that Dr. Goldwasser is uniquely qualified to provide.

In medical device product liability cases, there is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulation explicitly noted by Dr. Goldwasser states that information can be omitted from labeling:

> if, but only if, the article is a device for which directions, **hazards**, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added); *see also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine). Both the TVT and TVT-Exact IFUs restrict the class of surgeons who may use TVT and TVT-Exact. (*See* Ex. A, TVT IFU (English excerpts) at ETH.MESH.05225382; Ex. B, TVT-Exact IFU (English excerpts) at ETH.MESH.05799238.) The TVT-Exact IFU, for example, advises that "Users should be familiar with surgical technique for SUI Sling placement and should be adequately trained in implanting the GYNECARE TVT EXACT™ Continence System before employing it." (Ex. B, TVT-Exact IFU at ETH.MESH.05799238.) Accordingly, plaintiffs' failure to warn claim depends on what

"hazards" were "commonly" known to surgeons familiar with pelvic floor repair as well as non-absorbable meshes.

This Court has made clear that a physician may draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See, e.g.*, *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Winebarger*, 2015 WL 1887222, at *15 (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the completeness of IFUs from a clinical perspective, despite lack of expertise with FDA regulations and requirements for warnings, or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding Dr. Galloway qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

Akin to Drs. Shull and Galloway in *Winebarger*, it is proper for Dr. Goldwasser to use his clinical experience and examination of a large pool of scientific literature to identify the risks that are commonly known to pelvic floor surgeons and give an opinion about whether risks allegedly omitted from the IFU were nonetheless commonly understood as existing risks from *a clinical perspective*:

> As I have already noted above, all pelvic floor surgical procedures have certain commonly known risks. And the risks associated with the TVT and TVT-Exact procedures are almost all common to any pelvic floor surgery regardless whether mesh is utilized. These risks have been discussed in medical literature discussing pelvic floor surgeries for decades. It is commonly known that any surgery for stress urinary incontinence can potentially cause complications such as pelvic

> pain, nerve/vessel injury, scarring, wound complications, bleeding, damage to surrounding organs, voiding problems/retention, dyspareunia, de novo or worsened incontinence, and the need for re-operation due to complications. Surgeons also commonly know that these complications can be mild, moderate, or severe, and temporary or long-term.

(Pls.' Ex. B (Goldwasser Report) 32-33; Pls.' Ex. D (Goldwasser Dep.) 69:15-19.) This opinion is particularly appropriate given that Dr. Goldwasser uses his knowledge and experience as an instructor to train young doctors in their residency. It is a far cry from Plaintiffs' argument that Dr. Goldwasser has opined on the adequacy of the TVT's and TVT-Exact's IFUs' compliance with regulatory requirements and medical device industry practices and lacks the qualifications to do so. (*See* Pls.' Memorandum at 5.)

Nevertheless, Plaintiffs may incorrectly argue for the first time on reply that the above opinion is precluded by this Court's rulings in *Tyree* and *Bellew*. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D. W. Va. 2014); *Bellew v. Ethicon*, Inc., No. 2:13-cv-22473, Dkt. 265 at 33 (S.D. W. Va. Nov. 20, 2014). But, as is made clear above, Dr. Goldwasser's opinions rest not only on his own practice but on his historical review of the medical literature as well as his own experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. This makes him well qualified to testify as to what risks are associated with mesh implants, and whether those risks are disclosed in the IFU or are otherwise "commonly known" to those surgeons. Notably, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible

testimony. That Plaintiffs may disagree with Dr. Goldwasser's conclusion goes to weight, not admissibility and can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

Simply put, it is disingenuous for Plaintiffs to suggest that Dr. Goldwasser's opinions are based solely on his personal experience. Even Plaintiffs' excerpts of Dr. Goldwasser's deposition transcript reference that he "relied not only on his personal, clinical experience, but also on the peer-reviewed literature[.]" (Pls.' Memorandum at 6.) He *does not* testify that his opinions are based *only* on his personal experience. In the cited testimony, Dr. Goldwasser confirms that his report is based on various literature, some of which were provided by Ethicon and others he obtained on his own. (*Id.*) In fact, Plaintiffs took issue with one article that Dr. Goldwasser relied on and questioned his failure to consider another article that purports to illustrate statistically significant incidence rates that Ethicon failed to include in its IFUs. (*Id.* at 7-8.) Yet, when Plaintiffs asked about this article, Dr. Goldwasser responded that the incidence rate was "inconsequential clinically." (Pls.' Ex. D (Goldwasser Dep.) 80:9-16.) In short, Plaintiffs have only provided an outline for cross-examination, not an argument for inadmissibility under *Daubert*. *See, e.g.*, *Trevino*, 2016 WL 2939521, at *40 ("If there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination."); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 ("Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility."). Dr. Goldwasser's IFU opinions should be held admissible.

II. Dr. Goldwasser is well qualified to offer his opinions on the physical properties of polypropylene mesh and supports them with a reliable methodology.

Plaintiffs attempt to argue that Dr. Goldwasser should not be permitted to offer opinions on the physical properties of polypropylene mesh "because personal, clinical experience is not an

adequate foundation for such testimony." (Pls.' Memorandum at 9.) Contrary to Plaintiffs' arguments, however, Dr. Goldwasser is qualified to offer these opinions based on his clinical practice and review of medical literature. *See In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 159 (D. Mass. 2009). While Dr. Goldwasser may not be a biomaterials expert, he can give *clinical* opinions on degradation, contracture, cytotoxicity, and mechanical and laser cut mesh based on his clinical experience implanting the mesh, studying its properties, teaching its use by surgeons, and review of the medical literature and medical society materials. Indeed, Dr. Goldwasser's report and disclosures reference and rely on extensive relevant literature on these very subjects. (*See generally* Pls.' Ex. B (Goldwasser Report); Pls.' Ex. E (General Reliance List); Pls.' Ex. F (Supplemental Reliance List).)

A. Dr. Goldwasser's testimony regarding degradation, mesh contraction and appropriate pore weight and size is reliable and admissible.

Dr. Goldwasser opined that "my clinical experience and analysis of the body of data, including the studies cited in my report, supports my opinion that Ethicon's polypropylene mesh does not degrade in vivo, or if does, that such degradation does not have any clinically significant effect." (Pls.' Ex. B (Goldwasser Report) at 29-30.) He also opined that "[i]n my practice, I have not seen a single case of contraction, and I am not aware of any literature that describes contraction associated with TVT or TVT Exact" and that pore size "can impact infectious risk and tissue integration." (*Id.* at 9, 27.) Plaintiffs argue that Dr. Goldwasser is not qualified to offer these opinions and that he offers no reliable methodology for them. These arguments should be rejected.

Dr. Goldwasser is qualified to offer his opinions. In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S. Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years was qualified to opine

that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 WL 2124991, at *28 (S.D. W. Va. May 6, 2015). Like Dr. Green, Dr. Goldwasser has sufficient familiarity and experience with transvaginal mesh generally and the TVT and TVT-Exact in particular to provide reliable opinions on whether they shrink, contract, or degrade. Dr. Goldwasser has implanted over a thousand TVT procedures (mainly TVT and TVT-Exact), and when mesh complications arise, he treats and manages those complications. (Pls.' Ex. B (Goldwasser Report) at 4 (stating that Dr. Goldwasser's practice also involves "treating and managing complications associated with both **mesh** and non-mesh surgical procedures." (emphasis added).); Pls.' Ex. D (Goldwasser Dep.) 121:13-122:16.) He also has "considerable experience treating complex female pelvic pain, sexual dysfunction, complex urinary incontinence, recurrent urinary tract infections, and other pelvic complaints in patients." (Pls.' Ex. B (Goldwasser Report) at 4-5.) Dr. Goldwasser is therefore qualified to opine that TVT and TVT Exact do not degrade, contract, or cause infections.

Further, Dr. Goldwasser has demonstrated the reliability of his methodology. This Court, in *Mathison*, also found that the doctor's clinical experience and review of scientific literature were sufficiently reliable bases in forming his opinions about the mesh product's physical properties. *See Mathison*, 2015 WL 2124991, at *28. Similarly, here, in addition to his extensive clinical experience, Dr. Goldwasser reviewed over 900 articles in his General Reliance List, which directly contradicts Plaintiffs' argument that he "pick[s] and choose[s]" his articles. Dr. Goldwasser's deposition testimony confirms that he is knowledgeable regarding the substance of the literature. (*See, e.g.*, Pls.' Ex. D (Goldwasser Dep.) 74:1-82:18.) Thus, Dr. Goldwasser's clinical experience and, in particular, his review of the scientific literature

adequately qualifies him to opine on the physical properties of TVT and TVT-Exact, including degradation, contraction, and pore weight and size.

This is consistent with prior rulings in this MDL, where this Court has allowed urologists, gynecologists, and urogynecologists with extensive experience in treating stress urinary incontinece, including the mesh devices at issue, to testify that they have not experienced certain alleged physical properties (such as degradation) in the mesh devices at issue. *See, e.g.*, *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016) (finding that a practicing urogynecologist who is board-certified in obstetrics and gynecology and had extensive experience in treating stress urinary incontinence and pelvic organ placing, including Prefyx and Uphold mesh slings, was "qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices."); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); Huskey, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], at 6–9. Accordingly, Plaintiffs' request to exclude Dr. Goldwasser's opinion on degradation and mesh contraction should be dismissed.

B. Dr. Goldwasser should be permitted to testify on cytotoxicity and cancer risk.

Dr. Goldwasser opined that "I am not aware of any evidence that polypropylene, when used as designed for its intended purpose as a mesh implant or as a suture material, has any

clinically significant cytotoxic or cancer-causing effect." (Pls.' Ex. B (Goldwasser Report) at 30.) Plaintiffs contend that Dr. Goldwasser cannot offer such opinions because he is not an expert in gynecology oncology and he received no training in it. (Pls.' Memorandum at 12-13.) Although Dr. Goldwasser may not be a gynecological oncologist, he was formally trained in it. (Pls.' Ex. D (Goldwasser Dep.) 14:24-15:2 ("Q. Gynecological oncology, did you receive specific formal training in that as part of your residency and/or fellowship? A. In residency.").) Because of his clinical experience, which incorporates his gynecologic oncology training, Dr. Goldwasser is adequately qualified. Further, his report identifies relevant literature on this topic. (*See, e.g.*, Pls.' Ex. B (Goldwasser Report) at 31 (citing article that concludes polypropylene is not associated with carcinogenesis.) Dr. Goldwasser's review of relevant literature and reliance on them, combined with his experience as a surgeon, teacher, inventor, provide a reliable basis for his opinions on cytotoxicity and cancer risks.

C. Dr. Goldwasser is qualified to offer his opinions on the lack of clinical distinction between mechanical cut and laser cut mesh.

Dr. Goldwasser's extensive clinical experience using mesh and review of the relevant literature qualifies him to call into question Plaintiffs' scientific basis for their assertion that Ethicon created laser-cut mesh in response to alleged clinical problems from mechanical cut mesh. Dr. Goldwasser opined that in his practice, he has not noted any clinical difference between the two types of mesh and continues to have no preference between the two. (Pls.' Ex. B (Goldwasser Report) at 28.) He also indicated that he reviewed clinical studies on TVT, "which consistently demonstrate its efficacy, durability and safety [and] have not been shown to have a difference in results pre and post 2007 when laser cut mesh became available." (*Id.*) Moreover, when questioned on the subject at his deposition, Dr. Goldwasser testified that he reviewed Ethicon's company documents which found no "clinical relevance" between

mechanical cut and laser cut mesh. (Pls.' Ex. D (Goldwasser Dep.) 136:18-137:17.) Thus, Plaintiffs' Motion on this point should be rejected for substantially the same reasons outlined in Point II (A).

III. Dr. Goldwasser's unfamiliarity with Boston Scientific's ProteGen sling is irrelevant to his qualifications to testify regarding the TVT and TVT-Exact.

As if an afterthought, Plaintiffs attempt to summarily suggest that because Dr. Goldwasser was unfamiliar with Boston Scientific's ProteGen sling, which was a "predicate device" for TVT's 510(k) clearance in 1997, he is not qualified to opine and testify on TVT and TVT-Exact. (Pls.' Memorandum at 15.) Any such argument should be denied because it is wholly irrelevant to *Daubert* scrutiny. The ProteGen sling is a completely distinct product created by a different manufacturer. Although the ProteGen sling was listed as a predicate device for TVT, only three aspects of the 510(k) submissions were similar: (1) the intended use as a pubourethral sling to treat stress urinary incontinence, (2) the clinical mechanism of "urethral support," and (3) a similar incision location in the anterior vaginal wall. All other aspects of the devices were and are different. Indeed, the conditions that ultimately led to ProteGen's recall in 1999 stemmed from its differences from TVT, not its similarities. Nevertheless, nothing about the recall of the ProteGen sling speaks to Dr. Goldwasser's qualifications to opine and testify about TVT and TVT-Exact. Plaintiffs' Motion on this point should therefore be denied.

IV. Dr. Goldwasser's alleged "bias" against "attorney advertising" is, at most, an issue for cross-examination.

In their moving papers, Plaintiffs expend substantial ink arguing that Dr. Goldwasser's opinions are unreliable and should be discounted because he is "biased" against "attorney advertising" in the transvaginal mesh litigation. (Pls.' Memorandum at 15-18.) But, such an attack only goes to the weight of Dr. Goldwasser's testimony, not its admissibility. Plaintiffs can

test any alleged bias Dr. Goldwasser has through cross examination. *See Holcomb v. Boston Scientific Corp.*, 2016 WL 3189787, at *17 (S.D. W. Va. June 7, 2016) ("Bias and witness credibility are appropriate topics for cross-examination."). Thus, Plaintiff's Motion as to this argument is unavailing under *Daubert* and should be denied.

CONCLUSION

For the foregoing reasons, the Court should DENY Plaintiffs' motion to exclude or otherwise limit the opinions and testimony of defense expert Steven Goldwasser, M.D., in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 29, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
Kelly S. Crawford

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Exhibit A

continenza urinaria femminile causata da ipermobilità uretrale e/o della deficienza intrinseca dello sfintere. L'introduttore e la guida rigida per catetere TVT sono disponibili come articoli separati e servono a facilitare la collocazione del dispositivo TVT.

ISTRUZIONI PER L'USO

Normalmente la procedura viene eseguita in anestesia locale; tuttavia, è possibile ricorrere anche ad anestesia regionale o generale. L'entità della dissezione è minima: un ingresso vaginale nella linea mediana con una piccola dissezione per la prima posizione dell'ago, e due incisioni cutanee soprapubiche della pelle.

Con una pinza, afferrare la parete vaginale sui due lati dell' uretra. Con un piccolo bisturi, fare un'incisione sagittale lunga circa 1,5 cm, partendo da circa 1 cm dal meato uretrale esterno. L'incisione coprirà la zona uretrale mediana e consentirà il successivo passaggio del nastro. Con un paio di forbicine smusse, si eseguano due piccole dissezioni paraуretrali (di circa 0,5 cm) che permettano l'introduzione della punta dell'ago. Si eseguano poi due incisioni di 0,5-1 cm sulla pelle dell'addome, una su ciascun lato della linea centrale, **immediatamente sopra** la sinfisi, a non più di 4-5 cm di distanza l'una dall'altra. Il posizionamento dell'incisione e il passaggio dell'ago vicino alla linea centrale e alla parte posteriore dell'osso pubico sono importanti in modo da evitare di incidere su strutture anatomiche nella regione inguinale e nella parete pelvica laterale.

Inserire la guida rigida per catetere TVT nel canale del catetere di Foley (18 French). Il manico della guida è fissato attorno al catetere, in prossimità dell'allargamento. Lo scopo della guida è quello di allontanare il collo della vescica e l'uretra dal punto in cui la punta dell'ago passerà nello spazio retropubico. Con l'uso del catetere di Foley e della guida rigida per catetere, l'uretra e la vescica vengono spostate controlateralmente sul lato del passaggio dell'ago. Durante questo movimento, **la vescica deve essere vuota.** Avvitare l'estremità filettata dell'introduttore sull'estremità di uno degli aghi.

Usando l'introduttore, passare l'ago parauretralmente, penetrando il diaframma urogenitale. L'inserimento e il passaggio sono controllati con l'indice nella vagina sotto la parete vaginale, sul lato ipsilaterale e con la punta del dito sul bordo pelvico. La parte curva dell'ago deve essere in contatto con il **palmo** della mano "vaginale". Se si è destrimano, la mano sinistra è generalmente quella da usare per guidare l'ago. Con l'altra mano, afferrare **delicatamente** il manico dell'introduttore. Introdurre quindi la punta dell'ago nello spazio retropubico. Anche qui si dovrà osservare che ciò venga effettuato con il palmo della mano vaginale e con la punta dell'ago disposta in senso orizzontale, ossia nel piano frontale. Dopo aver oltrepassato il diaframma urogenitale si noterà che la resistenza al movimento sarà notevolmente ridotta. Guidare quindi immediatamente la punta dell'ago verso la linea centrale addominale ed abbassare il manico dell'introduttore premendo così la punta dell'ago contro la parte posteriore dell'osso pubico. Ora, muovere la punta dell'ago verso l'alto per portarla in corrispondenza dell'incisione nella pelle dell'addome, mantenendola in stretto contatto con l'osso pubico per l'intera corsa dell'ago.

Quando la punta dell'ago è arrivata all'incisione addominale, eseguire la cistoscopia per controllare l'integrità della vescica. Si deve vuotare la vescica dopo la prima cistoscopia. Ripetere la procedura sull'altro lato.

Tirare poi gli aghi verso l'alto per portare il nastro allentato, cioè non teso, sotto la parte centrale dell'uretra. Tagliare il nastro vicino agli aghi e regolarlo quindi in modo che la perdita sia limitata a non più di una o due gocce. Osservare le reazioni della paziente, per esempio tosse con la vescica piena (circa 300 ml) e chiudere temporaneamente e in maniera leggera l'incisione vaginale con una piccola pinza. Rimuovere quindi le guaine in plastica che circondano il nastro. **Durante la regolazione del nastro inserire delle forbicine smusse tra l'uretra ed il nastro onde evitare di tensionare il nastro stesso.** La rimozione anticipata della guaina può rendere difficili le successive regolazioni. Dopo aver regolato correttamente il nastro, chiudere l'incisione vaginale. Si devono quindi tagliare le estremità addominali del nastro, lasciandole sottocute. Non suturarle.

(GB) (USA) Tension-free Vaginal Tape (TVT) System — Instructions for Use

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

Important:
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer and reusable rigid catheter guide. **It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence).** The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION *(System)*

TVT consists of the following:

TVT Single-Use Device, provided sterile (available separately)

TVT Reusable Introducer, provided non-sterile (available separately)

TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately).

TVT DEVICE

The TVT device is a sterile single use device, consisting of one piece of undyed **PROLENE*** polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in **PROLENE*** polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. **PROLENE** mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER

The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE

The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter **(recommended size 18 French)** positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS

The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

INSTRUCTIONS FOR USE

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions.

Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5–1 cm are made, one on each side of the midline **just above** the symphysis not more than 4–5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, **the bladder should be empty.** The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethrally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should **rest in the palm** of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand grip the handle of the introducer **gently.** Now introduce the needle tip into the retropubic space. Once again observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced. Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is limited to no more than one or two drops. Use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. **To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths.** Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

Sistema con Nastro vaginale senza tensione (TVT) — Istruzioni per l'uso

Dispositivo TVT monouso
Introduttore poliuso per dispositivo TVT
Guida rigida poliuso per catetere TVT

Si prega di leggere attentamente tutte le istruzioni. Attenersi meticolosamente alle istruzioni per garantire un corretto funzionamento del dispositivo ed evitare qualsiasi lesione alla paziente.

Importante:
Questo foglio illustrativo ha il solo scopo di fornire le istruzioni per l'uso del nastro vaginale flessibile monouso, dell'introduttore poliuso e della guida rigida per catetere poliuso. **Non rappresenta una guida esauriente alla tecnica chirurgica da usare per correggere l'incontinenza urinaria da stress.** Il dispositivo deve essere usato solamente da medici pratici nel trattamento chirurgico dell'incontinenza urinaria da stress. Queste istruzioni sono raccomandate per l'uso generale del dispositivo. In procedure specifiche, l'uso del dispositivo può variare a seconda delle tecniche individuali adottate e dell'anatomia della paziente.

DESCRIZIONE *(Sistema)*

Il sistema TVT è composto da:

- Dispositivo monouso TVT, fornito sterile (disponibile separatamente)
- Introduttore poliuso TVT, fornito non sterile (confezione singola)
- Guida rigida per catetere poliuso TVT, fornita non sterile, confezione singola.

DISPOSITIVO TVT

Il dispositivo TVT è un dispositivo monouso, formato da un nastro di maglia in polipropilene (PROLENE*) non colorata (dimensioni: circa 1,1 x 45 cm), ricoperta da una guaina di plastica tagliata e sovrapposta al centro, e fermata da due aghi in acciaio inossidabile legati alla maglia e alla guaina con collari di plastica.

Il nastro in polipropilene (PROLENE*) è costituito da filamenti di trefoli di polipropilene estruso, lavorati a maglia, di composizione identica a quella della sutura chirurgica non assorbibile in polipropilene (PROLENE*). Il nastro ha uno spessore di circa 0,7 mm. Questo materiale, usato come sutura, ha dimostrato di avere caratteristiche non reattive e, in applicazioni cliniche, di mantenere la propria integrità indefinitamente. Il nastro in PROLENE* è lavorato con un processo che collega fra di loro le congiunzioni di ogni fibra e che conferisce elasticità in entrambe le direzioni. Questa proprietà elastica bidirezionale consente l'adattamento alle varie tensioni presenti nel corpo umano.

INTRODUTTORE TVT

L'introduttore TVT, fornito non sterile e poliuso, è in acciaio inossidabile e consiste di due pezzi: un manico, ed un'asta metallica filettata. L'introduttore, che serve a facilitare il passaggio del dispositivo TVT dalla vagina alla parete addominale, viene collegato e fissato all'ago attraverso l'estremità filettata dell'asta, prima di inserire l'ago con la striscia.

GUIDA RIGIDA PER CATETERE

La guida rigida per catetere TVT è uno strumento non sterile, poliuso, che serve a facilitare l'identificazione dell'uretra e del collo della vescica durante la procedura chirurgica. La guida viene inserita in un catetere di Foley **(misura raccomandata: 18 French),** posizionato nella vescica attraverso l'uretra. L'inserimento può essere facilitato lubrificando il catetere con gel.

INDICAZIONI

Il dispositivo TVT viene usato come bendaggio a fionda pubo-uretrale per la cura dell'incontinenza urinaria da stress, dell'in-

υπερήχων με φρέσκο διάλυμα απορρυπαντικού για περίπου 10 λεπτά ή ακολουθήστε τις παρακάτω οδηγίες αν ακολουθείτε ένα αυτόματο κύκλο πλυσίματος.

4. Ξεπλύνετε καλά σε άφθονο καθαρό νερό βρύσης και σκουπίσπε τα με μια πετσέτα. Μπορείτε να γρασάρετε τα εξαρτήματα του εργαλείου με ένα γράσο εργαλείων.

Αυτόματη Μέθοδος:
1. Ενδείκνυνται αυτόματοι κύκλοι πλύσης για τα ανοξείδωτα όργανα. Ένας συνιστώμενος κύκλος περιγράφεται παρακάτω:

- Κύκλος ξεπλύματος/βρεξίματος με κρύο νερό — 1 λεπτό
- Πλύσιμο σε θερμοκρασία 80 °C (176°F) — 12 λεπτά
- Κύκλος ξεπλύματος — 1 λεπτό
- Κύκλος ξεπλύματος — 12 λεπτά
- Τελικό ξέπλυμα — 2 λεπτά
- Ξέπλυμα με μηεταλλικό νερό 80 °C (176 °F) — 2 λεπτά
- Στέγνωμα σε 93 °C (199,4 °F) — 10 λεπτά

ΣΥΝΙΣΤΟΜΕΝΗ ΑΠΟΣΤΕΙΡΩΣΗ ΓΙΑ ΕΡΓΑΛΕΙΑ ΠΟΛΛΑΠΛΗΣ ΧΡΗΣΗΣ (Εισαγωγέα TVT και Οδηγού Δύσκαμπτου Καθετήρα TVT)

Ο Εισαγωγέας TVT και ο Οδηγός δύσκαμπτου καθετήρα TVT παρέχονται μη αποστειρωμένοι. Για να τα αποστειρώσετε, βάλτε τα σε αυτόκαυστο ατμού πριν από κάθε χρήση. Βάλτε τασε αυτόκαυστο ατμού σε θερμοκρασία 132 °C μέχρι 140 °C (270 °F μέχρι 284 °F) για τουλάχιστον 4 λεπτά (προ-εκκένωση). Αποτελεί ευθύνη του τελικού χρήστη να εξασφαλίσει την αποστείρωση του προϊόντος όταν χρησιμοποιεί τις συνιστώμενες διαδικασίες αποστείρωσης, καθότι ο εξοπλισμός βιοκαταστροφής και αποστείρωσης ποικίλλουν.

ΣΥΝΤΗΡΗΣΗ ΕΡΓΑΛΕΙΩΝ

- Εισαγωγέας TVT

Πρίν απο κάθε χρήση, ελέγχετε τα σπειρωτά μέρη των εσωτερικών αξόνων.

- Οδηγός Δύσκαμπτου Καθετήρα TVT

Πριν από κάθε χρήση, ελέγξτε το εργαλείο. Βεβαιωθείτε ότι το μακρύ άκρο που διαπερνά τον αγωγό του καθετήρα δεν έχει αιχμηρές άκρες ή ρινίσματα.

ΣΥΣΚΕΥΑΣΙΑ

Η συσκευή TVT παρέχεται αποστειρωμένη (με αιθυλενοξείδιο) για μία μόνο χρήση. Μην επαναποστειρώσετε. Μη χρησιμοποιήσετε το περιεχόμενο του πακέτου αν αυτό έχει ανοιχτεί ή καταστραφεί. Απορρίψτε τις ανοιχτές και αχρησιμοποίητες συσκευές.

Τα εξαρτήματα του εισαγωγέα TVT και του οδηγού δύσκαμπτου καθετήρα TVT πολλαπλής χρήσης παρέχονται ξεχωριστά και δεν είναι αποστειρωμένα. Τα εξαρτήματα αυτά πρέπει να καθαριστούν και να αποστειρωθούν πριν από κάθε χρήση όπως περιγράφεται πιο πάνω.

ΑΠΟΘΗΚΕΥΣΗ

Συνιστούμενες συνθήκες αποθήκευσης για τη συσκευή TVT μιας χρήσης είναι κάτω από 25 °C, μακριά από υγρασία και άμεση θερμότητα. Μη την χρησιμοποιήσετε μετά την ημερομηνία λήξης.

Προσοχή: Σύμφωνα με τον Ομοσπονδιακό (ΗΠΑ) νόμο η συσκευή αυτή μπορεί να πωληθεί μόνο από γιατρό ή κατόπιν συνταγής του.

Διανομέας:

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CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- **Do not use TVT procedure for patients who are on anti-coagulation therapy.**
- **Do not use TVT procedure for patients who have a urinary tract infection.**
- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

To ensure the reliability and functionality of the TVT Introducer and TVT Rigid Catheter Guide, clean the instrument before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instrument.

Prior to cleaning, the TVT introducer should be separated into its two component parts (handle and threaded shaft). The introducer is reassembled after cleaning and before sterilization.

Manual method

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

1. Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water — 1 minute
- Wash 176°F (80°C) — 12 minutes
- Rinse Cycle — 1 minute
- Rinse Cycle — 12 minutes
- Final Rinse — 2 minutes
- Rinse with Demineralized water 176°F (80°C) — 2 minutes
- Dry 199.4°F (93°C) — 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

The TVT Introducer and Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

περιοχές πρέπει να έχετε υπόψη σας ότι μια μελλοντική μόλυνση μπορεί να απαιτήσει την αφαίρεση του υλικού.

- Θα πρέπει να εφιστήσετε την προσοχή της ασθενούς ότι μία μέλλουσα εγκυμοσύνη μπορεί να αναιρέσει τα επιτεύγματα της χειρουργικής επέμβασης και η ασθενής μπορεί να γίνει και πάλι ακρατής.
- Κατά το μετεγχειρητικό στάδιο, ο ασθενής δεν πρέπει να σηκώνει βάρη και/ή πρέπει να απέχει απο δραστηριότητες επίπονης σωματικής άσκησης (π.χ. ποδηλασία, τρέξιμο) για τουλάχιστον τρείς η τέσσερις εβδομάδες, καθώς και απο σεξουαλική επαφή για ένα μήνα. Ο ασθενής μπορεί να επανέλθει στις φυσιολογικές του δραστηριότητες μετά απο μία ή δύο εβδομάδες.
- Θα πρέπει να εξηγήσετε στην ασθενή ότι αν παρουσι αστούν δυσουρία, αιμορραγία ή άλλα προβλήματα, θα πρέπει να επικοινωνήσει αμέσως με το χειρουργό της.
- Όλα τα χειρουργικά εργαλεία υπόκεινται στον κίνδυνο φθοράς και ζημίας υπό κανονική χρήση. Πριν το χρησιμοποιήσετε, ελέγξτε οπτικά το εργαλείο. Δεν θα πρέπει να χρησιμοποιείτε ελαττωματικά εργαλεία, ή εργαλεία που φαίνονται διαβρωμένα. Πετάξτε τα.
- Μη πιάνετε το πλέγμα PROLENE με συνδετήρες, κλιπς ή σφιγκτήρες γιατί μπορεί να του προκαλέσετε μηχανική βλάβη.
- Μην αποστειρώνετε τη συσκευή TVT. Πετάξτε τις ανοικτές, μη χρησιμοποιημένες συσκευές.

ΠΑΡΕΝΕΡΓΕΙΕΣ

- Κατά τη διέλευση της βελόνας, υπάρχει κίνδυνος διάτρησης ή ρήξης των κύριων αγγείων, των νεύρων, της κύστης ή του εντέρου. Στην περίπτωση αυτή, απαιτείται αποκατάσταση των τραυματισμένων οργάνων με χειρουργική επέμβαση.
- Μπορεί να επέλθει ένας πρόσκαιρος τοπικός ερεθισμός στην περιοχή της πληγής και μια πρόσκαιρη αντίδραση στο ξένο σώμα. Η αντίδραση αυτή μπορεί να προκαλέσει εξώθηση, διάβρωση, σχηματισμό συριγγίου και φλεγμονή.
- Όπως και όλα τα ξένα σώματα, το πλέγμα PROLENE μπορεί να επιδεινώσει μια ήδη υπάρχουσα μόλυνση. Το πλαστικό περίβλημα που καλύπτει αρχικά το πλέγμα PROLENE αποσκοπεί στον περιορισμό του κινδύνου αυτής της μόλυνσης.
- Η υπερβολική θεραπεία, δηλαδή η πολύ ισχυρή τάση που μπορεί να επιβληθεί στην ταινία μπορεί να προκαλέσει πρόσκαιρη ή μόνιμη έμφραξη της κάτω ουροφόρου οδού.

ΕΝΕΡΓΕΙΕΣ

Μελέτες επί ζώων έδειξαν ότι η εμφύτευση πλέγματος PROLENE προκαλεί μια ελάχιστη πρόσκαιρη φλεγμονώδη αντίδραση στους ιστούς, η οποία ακολουθείται από την εναπόθεση ενός λεπτού στρώματος ινώδους ιστού που μπορεί να αναπτυχθεί μέσω των διαστημάτων του πλέγματος και ως εκ τούτου να ενσωματώσει το πλέγμα σε γειτονικούς ιστούς. Το υλικό δεν απορροφάται ούτε διασπάται ή εξασθενεί από τη δράση των ενζύμων του ιστού.

ΟΔΗΓΙΕΣ ΚΑΘΑΡΙΣΜΟΥ ΕΡΓΑΛΕΙΩΝ ΠΟΛΛΑΠΛΗΣ ΧΡΗΣΗΣ (Εισαγωγέα TVT και Οδηγού Δύσκαμπτου καθετήρα TVT)

Για να εξασφαλίσετε τη σταθερότητα και την καλή λειτουργικότητα του Εισαγωγέα TVT και του Οδηγού Δύσκαμπτου καθετήρα TVT, καθαρίζετε το εργαλείο πριν την αρχική του χρήση και μετά από κάθε επέμβαση. Τα επόμενα αποτελούν υποδείξεις μεθόδων καθαρισμού του εργαλείου είτε με το χέρι είτε αυτόματα.

Πριν τον καθαρισμό, διαχωρίστε τον εισαγωγέα σαν δύο τμήματά του που τον αποτελούν (λαβή και σπειρωτός άξονας). Ξανασυναρμολογήστε τον εισαγωγέα μετά τον καθαρισμό και πριν την αποστείρωση.

Μέθοδος με το χέρι

1. Αφήστε το εργαλείο να μουλιάσει σε ένα απορρυπαντικό με ένζυμα κατάλληλο για εργαλεία από ανοξείδωτο ατσάλι.
2. Πλύντε σε ένα απορρυπαντικό και απολυμαντικό διάλυμα σε μια θερμοκρασία 30 °C μέχρι 35 °C (86 °F μέχρι 95 °F). Αφαιρέστε με μια μαλακή βούρτσα κάθε μόλυνση από υγρά σώματος ή ιστούς.
3. Τοποθετήστε τα εξαρτήματα του εργαλείου σε ένα λουτρό

ανεβάζετε. Όταν το άκρο της βελόνας φθάσει στην κοιλιακή εντομή, εκτελέστε μια κυστεοσκόπηση για να επιβεβαιώσετε την ακεραιότητα της ουροδόχου κύστης. Η ουροδόχος κύστη πρέπει να εκκενωθεί μετά απο την πρώτη κυστεοσκόπηση. Η διαδικασία επαναλαμβάνεται από την άλλη πλευρά.

Οι βελόνες τραβιούνται κατόπιν προς τα επάνω για να φέρουν την ταινία (επίδεσμο) ελεύθερη, δηλαδή χωρίς τάση, κάτω από την μεσουρήθρα. Κόψτε την ταινία σε μικρή απόσταση απο τις βελόνες. Τοποθετήστε την έτσι ώστε η διαρροή υγρών να περιοριστεί σε μία η δύο σταγόνες και όχι περισσότερο. Για να αποφύγετε το τέντωμα της ταινίας, πρέπει να τοποθετήσετε ένα μη αιχμηρό όργανο (ψαλίδι ή λαβίδες) μεταξύ της ουρήθρας και της ταινίας, καθώς την τοποθετείτε. Χρησιμοποιήστε την ανάδραση του ασθενή, π.χ. βήξιμο με γεμάτη ουροδόχο κύστη (περίπου) και κρατήστε την κολπική τομή προσωρινά κλειστή χωρίς να την πιάσετε πολύ σφιχτά χρησιμοποιώντας μικρές λαβίδες. Αφαιρέστε τα προστατευτικά καλύμματα που περιβάλλουν την ταινία. Η πρόωρη αφαίρεση του καλύμματος ενδέχεται να εμποδίσει τις υπόλοιπες διαδικασίες τοποθέτησης που ακολουθούν. Αφού τοποθετήσετε σωστά την ταινία, κλείστε την τομή του κόλπου. Κόψτε τα κοιλιακά άκρα της ταινίας και τοποθετήστε τα υποδερμικά. Μην τα ράβετε. Ράψτε τις τομές του δέρματος. Αδειάστε την ουροδόχο κύστη. Μετάτην παρούσα διαδικασία, κατά το μετεγχειρητικό στάδιο δεν απαιτείται καθετηριασμός. Ο ασθενής θα πρέπει να υποβληθεί στη διαδικασία εκκένωσης της κύστης 2-3 ώρες μετά την εγχείρηση.

ΑΝΤΕΝΔΕΙΞΕΙΣ

Όπως για κάθε χειρουργική ανάρτηση ενός οργάνου, αυτή η επέμβαση δεν πρέπει να πραγματοποιείται σε έγκυες ασθενείς. Επίσης, δεδομένου ότι το πλέγμα πολυπροπυλενίου PROLENE δε θα επεκταθεί σημαντικά, δε πρέπει να τοποθετείται σε ασθενείς με πιθανότητα μελλοντικής ανάπτυξης συμπεριλαμβανομένων των ασθενών με σκέψεις για μελλοντική εγκυμοσύνη.

ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΚΑΙ ΠΡΟΦΥΛΑΞΕΙΣ

- Μη χρησιμοποιείτε την επέμβαση TVT σε ασθενείς που ακολουθούν αναπηκτική θεραπεία.
- Μη χρησιμοποιείτε την επέμβαση TVT σε ασθενείς που πάσχουν από μόλυνση ουροφόρου οδού.
- Οι χρήστες πρέπει να είναι εξοικειωμένοι με τη χειρουργική τεχνική ανάρτησης τραχήλου της ουροδόχου κύστης πριν χρησιμοποιήσουν τη συσκευή TVT. Είναι όμως σημαντική η αναγνώριση ότι η μέθοδος TVT διαφέρει από την παραδοσιακή διαδικασία πλέγματος στο ότι η ταινία πρέπει να τοποθετηθεί χωρίς τάση κάτω από την μεσουρήθρα.
- Για την επέμβαση με τη συσκευή TVT θα πρέπει να ακολουθήσετε τις αποδεκτές χειρουργικές πρακτικές όπως και για τη θεραπεία μιασμένων ή μολυσμένων πληγών.
- Η μέθοδος TVT πρέπει να χρησιμοποιείται με προσοχή προκειμένου να αποφεύγεται η επαφή με τα κύρια αγγεία, τα νεύρα, την κύστη και το έντερο. Οι κίνδυνοι ατυχήματος μειώνονται όταν λαμβάνονται προφυλάξεις σε ό,τι αφορά την τοπική ανατομία και διασφαλίζεται η σωστή διέλευση των βελόνων.
- Αιμορραγία στον οπισθοηβικό χώρο σημειώνεται κατά το μετεγχειρητικό στάδιο. Ελέγξτε εάν υπάρχουν ενδείξεις ή εάν ο ασθενής παρουσιάζει τα σχετικά συμπτώματα, πριν την έξοδό του (από το νοσοκομείο.
- Πρέπει να εκτελέσετε μια κυστεοσκόπηση για να επιβεβαιώσετε την ακεραιότητα της ουροδόχου κύστης ή για να εντοπίσετε μια διάτρηση της ουροδόχου κύστης.
- Σπρώξτε μαλακά τον οδηγό του δύσκαμπτου καθετήρα μέσα στον καθετήρα Foley έτσι ώστε ο οδηγός του καθετήρα να μην επεκταθεί μέχρι τις τρύπες του καθετήρα Foley.
- Όταν αφαιρείτε τον οδηγό του δύσκαμπτου καθετήρα, ανοίξτε εντελώς τη λαβή ώστε ο καθετήρας να παραμείνει σωστά στη θέση του.
- Μην αφαιρείτε το πλαστικό κάλυμμα έως ότου η ταινία τοποθετηθεί σωστά.
- Βεβαιωθείτε ότι η ταινία τοποθετήθηκε με την ελάχιστη τάση κάτω από την μεσουρήθρα.
- Όταν τοποθετείτε το πλέγμα PROLENE σε μολυσμένες

INSTRUMENT MAINTENANCE

- TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.

- TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

HOW SUPPLIED

The TVT device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

The reusable TVT introducer and TVT rigid catheter guide accessories are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the TVT single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

EC
Legal Manufacturer
ETHICON SaRL
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Neuchatel, Switzerland

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ETHICON Ltd
Bankhead Avenue
Edinburgh, EH11 4HE
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Distributor (USA):
Gynecare
a division of Ethicon, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0151

Exhibit B

Gynecare

TVT EXACT™

Continence System

ENGLISH

Please read all directions, precautions, and warnings prior to use. Failure to properly follow instructions may result in improper functioning of the devices and/or may lead to injury. These instructions for use provide direction for using the GYNECARE TVT EXACT™ Continence System. This is not a technique manual nor a substitute for appropriate training and experience in surgical technique for correcting Stress Urinary Incontinence. The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in the use of the GYNECARE TVT EXACT™ Continence System. These instructions are recommended for general use of the GYNECARE TVT EXACT™ Continence System. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT EXACT™ Continence System consists of the following sterile, single-use components:

A. GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly (See Figure 1):

1. Implant
2. Implant Sheath
3. Trocar Sheath
4. Trocar Sheath Cut-out

The GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly consists of one piece of blue (Phthalocyanine blue, color index number 74160) PROLENE™ Polypropylene Mesh (Implant) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a clear plastic Implant Sheath and held between two white Trocar Sheaths, which are bonded to the Implant and Implant Sheath. PROLENE Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE™ Polypropylene Nonabsorbable Surgical Sutures. The Implant is approximately 0.027 inches (0.7 mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE Mesh is knitted by a process which interlinks each fiber junction.

B. GYNECARE TVT EXACT™ Continence System Trocar (See Figure 2):

5. Trocar Handle
6. Trocar Sheath Lock
7. Trocar Shaft

The GYNECARE TVT EXACT™ Continence System Trocar consists of the stainless steel Trocar Shaft and the plastic Trocar Handle. The Trocar Shaft is designed to fit inside the white Trocar Sheaths on the GYNECARE TVT EXACT™ Continence System Implant / Trocar Sheath Assembly, and is used to position the GYNECARE TVT EXACT™ Continence System Implant in the patient from a vaginal incision up through the abdominal wall.

GYNECARE TVT Reusable Rigid Catheter Guide

(available separately – not included in GYNECARE TVT EXACT™ Continence System)

The GYNECARE TVT Rigid Catheter Guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS

The GYNECARE TVT EXACT™ Continence System is intended to be used as a pubourethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT Rigid Catheter Guide is available separately and is intended to facilitate the placement of the GYNECARE TVT EXACT™ Continence System.

INSTRUCTIONS FOR USE

1. The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia.
2. Before the patient is prepped and draped, she should be placed in the lithotomy position, taking care to avoid hip flexion greater than 60°.
3. Insert an 18 French Foley catheter and leave it to open drainage.
4. At the level of the mid urethra, inject a small amount of local anesthesia submucosally to create a space between the vaginal wall and the periurethral fascia. The extent of dissection required for placement is minimal. Only a small paraurethral incision is required over the mid urethra to position the tip of the Trocar Sheath. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision no more than 1.5 cm long starting approximately 1.0 cm cephalad from the urethral meatus. This incision will be positioned over the mid-urethral zone and will allow for subsequent passage of the Implant.
5. With a small pair of blunt scissors, make two small paraurethral lateral dissections (approximately 0.5 to 1.0 cm) to accommodate the tips of the Trocar Sheaths.
6. Identify the two Trocar Sheath exit sites, which should be 2–2.5 cm on each side of the midline, immediately above the pubic symphysis (See Figure 3). Either mark these sites or, if desired, place two small 3–4 mm transverse stab incisions at the intended exit site. In order to avoid the inferior epigastric vessels it is important that the intended exit sites be not more than 2.5 cm from the midline. It is important that the exit sites for the Trocar Sheath passages be near the midline and close to the superior aspect of the pubic bone, in order to avoid anatomic structures in the abdomen, inguinal area and lateral pelvic sidewall.
7. If retropubic infiltration of local anesthesia is not performed then consider infiltrating the retropubic space with two injections of normal saline on either side of midline. Starting at the needle exit sites pass an 18 gauge needle along the back of the pubic bone until the tip of the needle touches the endopelvic fascia. As the needle is withdrawn inject 30 to 50 cc. By so doing it opens up the retropubic space to further minimize the risk of bladder puncture during retropubic Trocar passage.
8. Confirm that all urine has been drained from the bladder. Once the bladder is empty, insert the GYNECARE TVT Reusable Rigid Catheter Guide (available separately) into the channel of the 18 French Foley catheter. The handle of the GYNECARE TVT Reusable Rigid Catheter Guide should be fixed around the catheter at its proximal end. The purpose of placing the GYNECARE TVT Reusable Rigid Catheter Guide into the catheter is to allow contralateral displacement of the bladder, bladder neck and urethra away from the tip of the Trocar Sheath as it is passes through the retropubic space.
9. Place the Trocar Shaft inside one of the two white Trocar Sheaths (See Figure 4). Secure the Trocar Sheath to the Trocar Handle by hooking the Trocar Sheath Cut-out onto the Trocar Sheath Lock on the Trocar Handle (See Figure 5). NOTE: Ensure that the Trocar Sheath Cut-out goes completely over the Trocar Sheath Lock and is holding the Trocar Sheath on the Trocar Shaft securely. Be careful not to manipulate the Trocar Sheath appendage hanging past the Trocar Sheath Lock during the procedure, as that may result in the unintended disengagement of the Trocar Sheath Lock.
10. Gently push the tip of the 18 French Foley catheter toward the posterior lateral wall of the bladder opposite to the intended Trocar Sheath passage (See Figure 6). For example, by pushing toward the patient's left side the

bladder will go from a spherical to a spheroid configuration. This moves the bladder away from the back of the pubic symphysis (See Figure 7A and 7B). Additionally, it moves the bladder neck and the urethra to the left as the Trocar Sheath is passed on the patient's right side, thereby minimizing the risk of bladder perforation (See Figure 8A and 8B).

11. Hold the Trocar Handle using your dominant hand. Pass the tip of the white Trocar Sheath that has been mounted on the Trocar Shaft (see Step 8 above), paraurethrally through the urogenital diaphragm at the level of the midurethra. Initial insertion of the device is controlled by using the tip of the index finger of the non-dominant hand, which is placed in the vagina under the anterior vaginal wall, just lateral to the suburethral incision. The curved part of the Trocar Shaft should rest in the palm of the non-dominant hand. (See Figure 9). Pass the Trocar Sheath through the urogenital diaphragm into the retropubic space. During the initial placement into the paraurethral dissected space, the Trocar Sheath tip should be oriented horizontally, i.e. in the frontal plane. During passage through the urogenital diaphragm, lower the Trocar Handle to ensure that the Trocar Sheath Tip passes vertically while staying in close contact to the back of the pubic symphysis. After passage through the urogenital diaphragm resistance to the passage of the Trocar Sheath is significantly reduced once it enters the retropubic space.
12. At this point, the non-dominant hand is moved from the vagina to the suprapubic exit site. The Trocar Sheath tip is guided through the retropubic space staying as close to the back of the pubic symphysis as possible. This is achieved by lowering the Trocar Handle, thereby pressing the Trocar Sheath tip against the back of the pubic bone.
13. During passage through the retropubic space aim the Trocar Sheath tip towards the pre-marked abdominal exit site.
14. Move the Trocar Sheath tip upwards toward the abdominal skin exit sites keeping in close contact with the pubic bone until exiting the skin (See Figure 10). Once the Trocar Sheath tip exits the skin, grasp the exposed Trocar Sheath tip with a clamp. Release the Trocar Sheath from the Trocar Sheath Lock on the Trocar Handle by pushing the Trocar Sheath appendage laterally and off the Trocar Sheath Lock, and carefully withdraw the Trocar Shaft from within the Trocar Sheath. DO NOT PULL the Trocar Sheath up any further.
15. The procedure is now repeated on the patient's other side while repeating steps 9 – 14. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER NOW BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.
16. Once both white Trocar Sheaths have been passed and before the Implant is pulled into place, remove the 18 French Foley catheter and perform a cystoscopy (70 degree lens recommended).
17. Once bladder integrity is confirmed, gently pull the Trocar Sheaths upward to bring the Implant loosely (i.e. without tension) under the midurethra. Cut the Implant bilaterally close to the connection to the Trocar Sheaths. Adjust the Implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).
18. Grasp the Implant Sheaths that surround the Implant with clamps, taking care not to grasp the Implant. Then individually remove the Implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the Implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the Implant during removal of the Implant Sheaths.
19. **NOTE: Premature removal of the sheaths may make subsequent adjustments difficult.**
20. After proper adjustment of the Implant, close the vaginal incision. The abdominal ends of the Implant are then cut and left in the subcutis; do not suture the Implant.
21. Close the skin incisions with suture or surgical skin adhesive.
22. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty their bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT EXACT™ Continence System on patients who are on anti-coagulation therapy.
- Do not perform the GYNECARE TVT EXACT™ Continence System procedure on patients who have a urinary tract infection.
- Users should be familiar with surgical technique for SUI Sling placement and should be adequately trained in implanting the GYNECARE TVT EXACT™ Continence System before employing it. It is important that the Implant be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the GYNECARE TVT EXACT™ Continence System procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT EXACT™ Continence System procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of the Trocar Sheaths will minimize risks.
- Retropubic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the Foley catheter remains properly in place.
- Do not remove the Implant Sheath until the Implant has been properly positioned.
- Ensure that the Implant is placed with minimal tension under the mid-urethra.
- PROLENE Mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the GYNECARE TVT EXACT™ Continence System procedure, in case of pregnancy delivery via cesarean section is recommended.
- Post-operatively, the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding, or other problems occur, the patient should be instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the GYNECARE TVT EXACT™ Continence System procedure. To minimize this risk, make sure to place the Implant tension-free in the mid-urethral position.
- Do not contact the PROLENE Mesh with any staples, clips or clamps, as mechanical damage to the mesh may occur.
- Do not resterilize the GYNECARE TVT EXACT™ Continence System. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the implant may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE Mesh elicits a minimal inflammatory reaction in tissues and stimulates the deposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

STERILITY

The GYNECARE TVT EXACT™ Continence System is sterile if kept in original, unopened packaging. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

The reusable GYNECARE TVT Rigid Catheter Guide is supplied separately and is non-sterile. It is to be cleaned and sterilized prior to each use as described below.

INSTRUCTIONS FOR CLEANING GYNECARE TVT Rigid Catheter Guide (available separately)

To ensure the reliability and functionality of the GYNECARE TVT Rigid Catheter Guide, clean the instrument before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments.

Manual Method:

1. Soak the instrument in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument may be treated with instrument lubricant.

Automated Method:

Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176°F (80°C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176°F (80°C) – 2 minutes
- Dry 199.4°F (93°C) – 10 minutes

STERILIZATION RECOMMENDATIONS FOR GYNECARE TVT Rigid Catheter Guide (available separately)

The GYNECARE TVT Rigid Catheter Guide is supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

GYNECARE TVT Rigid Catheter Guide MAINTENANCE

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste. Please visit http://www.ethicon.com/recycling for more information.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), keep away from high moisture and direct heat. Do not use after expiration date.

SYMBOLS

Do not reuse/resterilize	Use by — year and month	CE 0086 CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
See instructions for use	STERILE EO Method of Sterilization – Ethylene Oxide	
REF Catalogue number	LOT Batch number	